K022712

MEDICAL DESIGNS LLC

Surgical Instruments Designed by Doctors

213 Sunset Drive
Brandon, SD 57005
Phone: (605)376-6008
Fax: (605)335-1489
E-mail: axt1@worldnet.att.net

NOV 12 2002

510(k) Summary

1. **Submitter Information:**
Medical Designs, LLC
213 Sunset Drive
Brandon, South Dakota 57005
(605) 376-6008
(605) 335-1489 Fax
e-mail: paxt@medicaldesignsllc.com

Contact: Mr. Paul John Axt
Preparation Date: August 13, 2002

2. **Trade Name**:
Hand Drill
(Catalog # 11-9901-7)

Common Name:
Cranial hand drill

Classification Name:
Drills, Burrs, Trephines & Accessories (Manual)

Classification:
The Medical Designs hand drill is a Class II device (21 CFR 882.4300)

3. **Predicate Device**:
Integra NeuroSciences Camino Hand Drill – Model 030 (K862160)

4. **Performance Standards**:
No applicable performance standards have been established by the FDA under Section 514 of the Food, Drug and Cosmetic Act

5. **Device Description**:
The hand drill consists of a black ABS plastic housing, glass filled nylon handle and ABS plastic handle knob. The hand drill has lubricated aluminum gears and a ¼" spring loaded, chrome plated steel, 3-jaw chuck assembly.

The hand drill is a single-use disposable device. It is sterilized using gamma radiation.

6. **Intended Use**:
The Medical Designs Hand Drill is intended for use in Neurosurgical procedures and for use with Medical Designs' Subdural Evacuating Port System (S.E.P.S.) Kit, Catalog # 11-9901.

The Hand Drill is not intended for any use other than that indicated.

7. **Biocompatibility**:
The materials used to manufacture Medical Designs' hand drill are identical to the materials used to manufacture the predicate device. When used as intended, neither the Medical Designs hand drill nor the predicate device come in direct contact with the body or bodily fluids.

8. **Summary of Substantial Equivalence**:
The Medical Designs hand drill has the same intended use as the Integra NeuroSciences Camino hand drill. Both are intended for use in Neurosurgery and Neurosurgical procedures.

The Medical Designs hand drill is made of the same materials and components as the predicate device and, therefore, does not raise new issues relating to the safety or effectiveness of its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 12 2002

Medical Designs, LLC
Paul John Axt
Vice President of Operations
213 Sunset Drive
Brandon, South Dakota 57005

Re: K022712
Trade/Device Name: Hand Drill, Model 11-9901-7
Regulation Number: 882.4300
Regulation Name: Drills, Burrs, Trephines and Accessories (Manual)
Regulatory Class: Class II
Product Code: HBG
Dated: August 13, 2002
Received: August 14, 2002

Dear Mr. Axt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Indications for Use

"The Medical Designs Hand Drill is intended for use in Neurosurgical procedures and for use with Medical Designs' Subdural Evacuating Port System Kit (S.E.P.S), Catalog # 11-9901."

"The Hand Drill is not intended for any use other than that indicated."

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022712